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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,090	03/01/2001	Yoav Eichen	18363.0002/P002	1528
24998	7590	03/07/2007	EXAMINER	
DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,090	EICHEN ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-9,18-20,22-29,35-39,41,43-45,47-51 and 53-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-9,18-20,22-29,35-39,41,43-45,47-51 and 53-63 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present Office Action is responsive to the Amendment received on December 5, 2006.

Preliminary Remark

Claims 2, 10-17, 21, 30-34, 40, 42, 46, and 52 are canceled.

Claims 53-63 are new.

Claims 1, 3-9, 18-20, 22-29, 35-39, 41, 43, 44, 45, 47-51, and 53-63 are pending and are under prosecution herein.

Claim interpretation

For the purpose of examination, the term, "target," has been assumed to be limited to biological molecules; and the term, "recognition moiety," has been also assumed to be limited to biological molecules, as when the claims are read in light of the specification, the terms are limited to the invention which pertains to biological molecules (i.e., nucleic acids, protein, antibody, etc.).

MPEP 608.01(o) states that the meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import.

This is necessary in order to insure certainty in construing the claims in the light of the specification, Ex parte Kotler, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901).

With regard to claim 21, the claim is drawn to a product, and the limitation imposed by claim 21 which recites an intended use, absent any physical recitation of the product that results in the intended use, does not confer any patentable weight.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 3-9, 18-23, 31, 33, 35-38, 41, 43, 44, and 52-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter, made in the Office Action mailed on June 5, 2006 is withdrawn in view of the Amendment received on December 5, 2006.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 3-5, 24-29, 35, 36, 39, 41, 43-45, 47-51, and 52 under 35 U.S.C. 102(b) as being anticipated by Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in Office Action mailed on June 5, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on December 5, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

In addition, the rejection of claims 55-57, 60, and 61 are included herein, as being necessitated by Amendment (by way of their addition).

The Rejection:

Braun et al. disclose a system/device and a method of their use comprising:

- (a) an assay device comprising one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety, said recognition moiety being oligonucleotides (page 777, 2nd column, 2nd paragraph);
- (b) an electric or electronic module arranged and configured to measure electric conductance;

(c) reagents comprising nucleation-forming entities and combination of metal ions, which detects target DNAs (column 777, 2nd column, *Silver deposition*); (Figure 1; Figure 4; page 775, 2nd column, 2nd paragraph; page 776, 1st column, 3rd paragraph), anticipating claims 1, 3-5, 24-25, 29, 35, 39, 41, 43, 44, and 45.

With regard to claim 36, Braun et al. disclose that the distance between the electrodes are between 12-16 μm .

Braun et al. disclose that the use of DNA polyanions as a template to fabricate a poly-(*p*-phenylene vinylene) (PPV) filament by attaching a positively charged *pre*-PPV polymer to be stretched DNA and subsequently treating it to form a highly photoluminescent PPV wire known (page 777, 1st column, 2nd full paragraph), anticipating claims 26, 27, and 28.

With regard to claims 47, 48, and 53, the recognition moiety is oligonucleotides (page 777, 2nd column, 2nd paragraph).

With regard to claims 49-51, the DNA being hybridized to is λ DNA (see page 777, 2nd column, 3rd paragraph, *Constructing the DNA bridge section*).

Therefore, Braun et al. anticipate the invention as claimed.

Response to Arguments:

Applicants contend that Braun et al. cannot anticipate the invention as claimed because Braun et al. do not teach or suggest a system or device having a means for determining whether one or more targets are in the sample as a result of the extent of electric conductance between the two electrodes of each assay set as amended in the claims (page 12, 5th paragraph, Response; page 13, 2nd paragraph, Response).

Applicants' argument is noted, but is not found persuasive.

What remains a fact, is that Braun et al. disclose a system comprising at least one set of electrodes, wherein said set of electrodes comprises spaced-apart nucleic acid probes (discussed above).

What remains a fact, is that Braun et al. disclose that the system allows for the conductance of electricity between said two electrodes, when a target nucleic acid comprising a sequence which complements both of said spaced-apart nucleic acid probes hybridizes thereto, thereby completing a circuit. In so far as claims drawn to a system is concerned, Braun et al. disclose all of the necessary components of the claimed invention. Whether one argues that one of the components can be used in a different application cannot confer patentability to a system comprising all of the components which are capable of achieving that application. In other words, Braun et al. disclose a system comprising a detector which can detect whether or not the circuit is completed. Whether one is contemplating using said detector for detecting a target nucleic acid cannot distinguish the claimed system because the detection is achieved by assaying for completion of a circuit through a detector, the detector of which is disclosed by Braun et al.

In addition, Applicants' arguments stating that the newly introduced limitation impose by the phrase, "where conductance above a threshold conductance indicates the presence of a respective target in a sample while conductance below a threshold conductance indicates the absence of any targets in the same" as amended in claims 24-26 (see page 14, 1st paragraph, Response).

This argument is not found persuasive because generically reciting that a system or method employs the step or a detector which allows the detection of a conductance above or below threshold conductance, cannot overcome the system and method disclosed by Braun et al., for the following reasons.

Braun et al. employ a method and a system which detects whether there is conductance between the two spaced-apart electrodes. One of ordinary skill in the art would know that such a threshold would be whether or not a circuit is completed. In other words, when circuit is completed, conductance is above a threshold, while when circuit is not completed, conductance is below a threshold.

Clearly, Braun et al. anticipate this embodiment as well.

Lastly, Applicants' arguments drawn to the limitation that Braun et al. do not teach a method for assaying the presence or absence of one or more biological molecule targets in a sample (page 12, bottom paragraph, Response), are also not found persuasive for the following reasons.

What remains a fact is that Braun et al. disclose that λ DNA comprise a target sequence which is sought by the two, spaced-apart nucleic acid probes, which are each immobilized on an electrode. Hence, by detecting whether the circuit is completed or not, one of ordinary skill in the art would have clearly recognized that the λ DNA was hybridized between the two, spaced-apart nucleic acid probes. Recognition of this fact, would relay to one of ordinary skill in the art that the target nucleic acid was present between the two electrodes.

The arguments are not found persuasive and the rejection is maintained therefore.

Claim Rejections - 35 USC § 103

The rejection of claims 31, 33, and 52 under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on June 5, 2006 is withdrawn in view of the Amendment received on December 5, 2006, canceling the rejected claims.

Rejection, Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 6-9, 18-21, 37, 38, and 54 under 35 U.S.C. 103(a) as being unpatentable over Braun et al. (Nature February 19, 1998, vol. 391, pages 775-778), made in the Office Action mailed on June 5, 2006 is maintained for the reasons already of record.

In addition, the rejection of claims 58, 59, 62, and 63 is included herein as being Necessitated by Amendment (e.g., by their addition).

Applicants' arguments presented in the Amendment received on December 5, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Braun et al. disclose a system/device and a method of their use comprising:

- (a) an assay device comprising one or more assay sets, each of the assay sets comprising at least two electrodes and a recognition moiety, said recognition moiety being oligonucleotides (page 777, 2nd column, 2nd paragraph);
- (b) an electric or electronic module arranged and configured to measure electric conductance;

(c) reagents comprising nucleation-forming entities and combination of metal ions, which detects target DNAs (column 777, 2nd column, *Silver deposition*) (Figure 1; Figure 4; page 775, 2nd column, 2nd paragraph; page 776, 1st column, 3rd paragraph).

Braun et al. disclose that the distance between the electrodes are between 12-16 □ m.

Braun et al. disclose that the use of DNA polyanions as a template to fabricate a poly-(*p*-phenylene vinylene) (PPV) filament by attaching a positively charged *pre*-PPV polymer to be stretched DNA and subsequently treating it to form a highly photoluminescent PPV wire known (page 777, 1st column, 2nd full paragraph).

The system/device and the method of their use disclosed by Braun et al. are drawn to a single assay set, that is, a system/device/method comprising two electrodes each of which comprise an oligonucleotide immobilized thereto; and the artisans do not explicitly disclose a system/device comprising multiple assay sets.

It would have been *prima facie* obvious to one of ordinary skill in the art to duplicate the assay set of Braun et al. to arrive at the claimed invention of a system/device comprising multiple assay sets and the method of their use for the following reasons.

In *in re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), the court expressed that duplication of parts, in the instant situation, the duplication of the assay set of Braun et al., has no patentable weight unless a new and unexpected result is provided.

In the instant situation, one of ordinary skill in the art would have clearly expected that the duplication of the assay set of Braun et al. would have resulted in the multiple and simultaneous detection of targets in sample, as devices comprising a plurality of binding sites has been well known and established in the art of biological detection (*i.e.*, Affymetrix®).

With regard to claims 6-9, while Braun et al. are not explicit in employing other well known metal particles which conduct electricity, such as platinum or gold, for the purpose of “metallizing” the bridge formed between the electrodes of Braun et al., one of ordinary skill in the art would have recognized that any well known colloidal metal particles would have produced such “conductive bridge,” which allows the electricity to pass between the electrodes of Braun et al. One of ordinary skill in the art would have had a reasonable expectation of success at such modification given that Braun et al. already disclose that silver, another well known colloidal metal particle have been employed in generating a “conductive bridge.”

With regard to claim 54, the recognition moiety employed by Braun et al. is oligonucleotide (or nucleic acid).

Therefore, the invention as claimed is *prima facie* obvious over Braun et al.

Response to Arguments:

Applicants present no new arguments drawn to the present invention than those which were fully addressed above. Therefore, the present rejection is maintained for the reasons already of record and the rebuttal above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

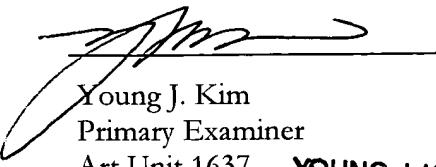
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group receptionist whose telephone number is
(571) 272-1600.



Young J. Kim
Primary Examiner
Art Unit 1637 **YOUNG J. KIM**
3/5/2007 **PRIMARY EXAMINER**

YJK